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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHARON MI LYN TAN

Appeal 2009-0508
Application 10/690,436
Technology Center 3700

Decided¹: April 23, 2009

Before JAMESON LEE, SALLY GARDNER LANE and SALLY C.
MEDLEY, *Administrative Patent Judges*.

MEDLEY, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The two month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

A. STATEMENT OF THE CASE

Boston Scientific Scimed Inc. (“Boston Scientific”), the real party in interest, seeks review under 35 U.S.C. § 134(a) of a Final Rejection of claims 1-26. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

References Relied on by the Examiner

Fields et al. (“Fields”)	5,357,961	Oct. 25, 1994
Fischell et al. (“Fischell”)	5,413,561	May 9, 1995
Davidson	5,588,443	Dec. 31, 1996
Liu et al. (“Liu”)	6,371,944	Apr. 16, 2002

The Rejections on Appeal

The Examiner rejected claims 1-26 under 35 U.S.C. § 103(e) as unpatentable over Liu, Davidson, and Fischell or Fields.

Claims 1-26 stand or fall together. (App. Br. 4).

The Invention

Referring to figure 2, [numbers from figure 2 inserted], Boston Scientific discloses an infection management system. The system includes a catheter [8], a side arm tube [13], a one way valve [14], and an antimicrobial intervention device [15] (i.e., rod) with a cap [16] located at its proximal end. (Spec. 3-6).

Boston Scientific’s figure 2 is reproduced below:

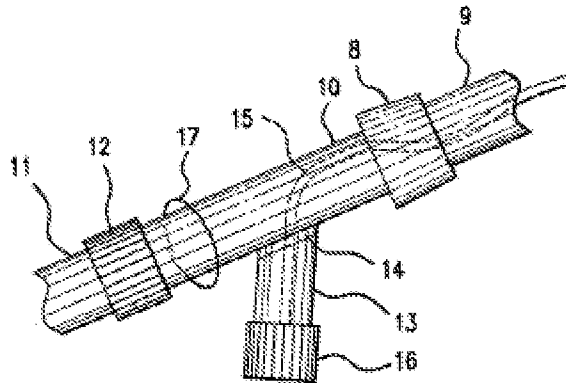


Figure 2 depicts a catheter with a side arm and rod.

Claim 1, reproduced from the Claim Appendix of the Appeal Brief, is as follows:

An infection management system, comprising:
a catheter with a lumen extending therethrough;
a side-arm tube extending laterally from a side of the catheter, wherein
the side-arm tube is located in a region of the catheter which remains outside a patient's body, and
a lumen through the side-arm tube communicates with the catheter lumen;
a one-way valve which prevents fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the catheter lumen;
an antimicrobial agent-bearing intervention device configured to be inserted through the side-arm tube lumen and the one-way valve into the catheter lumen; and
a cap coupled to the antimicrobial agent-bearing intervention device, the cap being configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

B. ISSUES

1. Has Boston Scientific demonstrated that Liu does not describe a catheter?

2. Has Boston Scientific demonstrated that the Examiner erred in determining that the claimed invention would have been obvious based on the rationale provided by the Examiner for combining the references?

C. FINDINGS OF FACT

1. A catheter is defined as “[a] tubular instrument to allow passage of fluid from or into a body cavity or blood vessel.” Stedman’s Medical Dictionary (Lippincott, Williams &Wilkins) (27th ed. 2004).

2. One of ordinary skill in the art at the time the invention was made would have recognized the benefit of providing an additional seal to prevent blood loss for redundancy should the first seal unexpectedly fail.

Boston Scientific's Disclosure

3. Referring to figure 2 above, [numbers from figure 2 inserted], Boston Scientific describes that catheter body [9] may alternatively be removably coupled at its distal end to a catheter previously implanted in the patient. (P. 5, l. 30-p. 6, l.1)

Liu

4. Referring to figure 1B, [numbers from figure 1B inserted], Liu describes an apparatus that includes a receptacle portion [1] such as a syringe, a connecting portion [2] having a common passage [10] from a first conduit to the receptacle portion, a first entry [3] for attachment to the receptacle, a second entry [4] into a second conduit [9] and a third entry [8] which opens to the first conduit such as a needle³ that is inserted into a blood vessel. (Col. 3, ll. 6-19).

Liu's Figure 1B, is reproduced below:

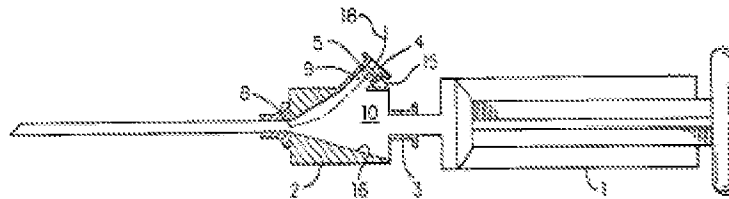


Figure 1B depicts a needle, a connecting portion and a syringe.

³ Although not shown in Liu's Figure 1B, the needle is referred to as element 7, as is shown in the Liu prior art Figure 1A. Col. 2, ll. 47-50.

5. A flexible linear object such as a guide wire [18] can be inserted into and through the second entry [4] and into the lumen of a conduit such as a needle. (Col. 3, ll. 12-15).
6. Second entry [4] has a one-way valve [5], such as a flap valve which prevents backup and escape of fluids such as blood through the second entry. (Col. 2, ll. 50-59, col. 3, ll. 15-17).
7. Referring to figure 2B, [numbers from figure 2B inserted], Liu describes that it is possible to use the invention by means of a separate adapter having three entries [11], [12], [13]. (Col. 4, ll. 10-15).

Liu's Figure 2B, is reproduced below:

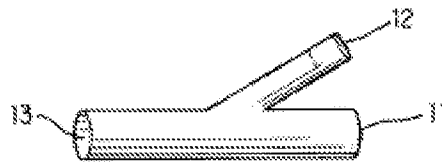


Figure 2B depicts an adapter.

8. Third entry [13] is used for connection to a conduit. (Col. 4, ll. 10-15).
9. Liu further describes that “[u]sing the separate adapter, the method of the invention can be practiced using standard equipment such as needles, catheters and wires found in most health care facilities.” (Col. 5, ll. 15-18).

Davidson

10. Davidson describes a guidewire [40] which can be coated with antibiotic, anticoagulants, for reducing platelet adhesion, or reducing other adverse cellular or tissue responses to surfaces in contact with blood. (Col. 4, ll. 25-35).

Fischell

11. Referring to figure 7 below, [numbers from figure 7 inserted], Fischell describes a catheter [20], [70] with a sealing cap [80] having a hemostasis valve [85] for coupling with a guidewire. (Col. 3, ll. 1-44, col. 4, ll. 38-43, 55-57).

Fischell's figure 7 is below:

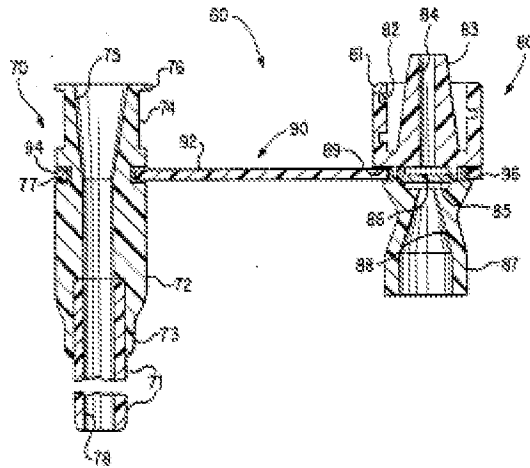


Figure 7 depicts a catheter with a sealing cap.

Fields

12. Referring to figure 1 below, [numbers from figure 1 inserted], Fields describes a three-way connector [15] including an insertion port [18], a flushing port [24] and an outlet port [21] which is connected to a catheter [30]. (Col. 4, ll. 38-60).

Fields' figure 1 is below:

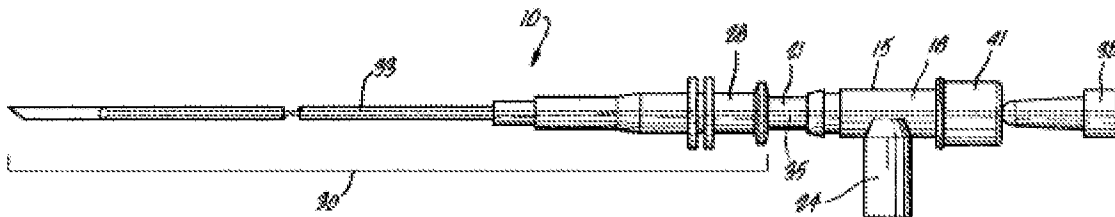


Figure 1 depicts a catheter and three-way connector.

13. A reclosable septum [41] is disposed on the insertion port [18], but enables a guidewire [35] to pass through the septum [41]. (Col. 4, ll. 59-60, col. 5, ll. 7-33).
14. Guidewire [35] includes a handle [38] at its end which provides a gripping surface that is larger than the guidewire and makes guidewire handling easier. (Col. 4, l. 66-col. 5, l. 4).
15. The handle [38] also acts as a stop to fix the position of the guidewire [35] in relation to the tip of a catheter. (Col. 5, ll. 4-6, 12-19).

D. PRINCIPLES OF LAW

In *KSR*, the Supreme Court rejected the rigid application of the “teaching suggestion or motivation” (TSM) test, instead favoring the “expansive and flexible approach” used by the Court. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). Based on its precedent, the Court reaffirmed the longstanding principle that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416.

In *KSR*, the Court instructed that in an obviousness analysis, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. *Id.* at 418. The Court also explained that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 421.

E. ANALYSIS

Independent claim 1 is representative and recites a “system comprising: a catheter . . . a sidearm extending laterally from a side of a catheter . . .”. (App. Br. 9).

The Examiner finds that Liu's needle [7] is a catheter. (Final Rejection 2; Ans. 4; FF⁴ 4). The Examiner also relies on Liu's connecting portion [2] for its second conduit [9], and one-way valve [5] to meet the claim limitations of the side-arm tube, side-arm tube lumen and one-way valve. (Final Rejection 2; Ans. 4; FF 4).

Boston Scientific argues that one skilled in the art would understand that Liu's needle is not a catheter. (App. Br. 5; Reply Br. 1). The argument is plausible. However, we need not determine whether one of ordinary skill in the art would have considered a needle to be a catheter. A prior art reference is available for all that it teaches. *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). In addition to the Examiner's findings, Liu describes an additional embodiment in which an adapter, i.e., a catheter, is separable and therefore not attached or necessarily integrated with a needle.

Liu's separate adapter, shown in figure 2B, has similar features to the connecting portion [2] of the embodiment relied upon by the Examiner except that it is separate from and not integral with a needle. (FFs 4, 7-9). The adapter of figure 2B, like connecting portion [2], has one-way valve and a second conduit and therefore meets the claim limitations of a side-arm tube, side-arm tube lumen and one-way valve. The separable adapter body is a tubular instrument that allows passage of fluid from or into a body cavity or blood vessel and is therefore a "catheter" as defined. (FF 1). The structure of the stand alone adapter of figure 2B does not necessarily depend on the integration with a needle. Therefore, Boston Scientific's argument

⁴ FF denotes Finding of Fact.

that Liu's needle [7] is not a catheter is of no moment, since Liu describes other embodiments where a needle is not integral with the "catheter" body.

Moreover, Liu's separable adapter is similar to Boston Scientific's catheter body [9], which may be removably coupled to a further catheter. (FF 3). One of ordinary skill in the art at the time of the invention would have recognized that Liu's adapter could have been connected to a further tubular structure or another catheter body and not necessarily connected to a needle, similar to Boston Scientific's disclosed embodiment. Liu suggests as much when it describes that the adapter's third entry [13] is for connecting to a first conduit and that "[u]sing the separate adapter, the method of the invention may be practiced using standard equipment such as needles, syringes, *catheters* and wires found in most health care facilities." (FFs 8-9, emphasis added). The Fischell and Fields references relied on by the Examiner provide additional evidence to demonstrate that one of ordinary skill in the art would have known that Liu's adapter could have been connected to a further tubular structure or catheter. Both references show a further tubular structure or catheter attached to an adapter similar to Liu's. (See Fischell fig. 6A, col. 4, ll. 18-22; and FF 12).

For all these reasons, Boston Scientific has not demonstrated that Liu does not describe a catheter.

Claim 1 further recites "an antimicrobial agent-bearing intervention device . . . and a cap coupled to the antimicrobial agent-bearing intervention device . . .". (App. Br. 9).

The Examiner finds that the combination of Liu and Davidson describes an antimicrobial agent-bearing intervention device; but not a cap coupled to the intervention device. (Final Rejection 2-3; Ans. 4; see FFs 4-

5, 10). The Examiner finds that Fischell teaches a cap [80] coupled to a guidewire in order to provide a handle or seal at the port end. (Final Rejection 3; Ans. 4; FF 11). Alternatively, the Examiner finds that Fields teaches an intervention device or guidewire [35] having a cap [38] for manipulation of the intervention device and for sealing against the port and for stopping the guidewire at a fixed location relative to the catheter. (Final Rejection 4; Ans. 5-6; FFs 14-15). The Examiner determined that the combination of Liu, Davidson and Fischell and the combination of Liu, Davidson and Fields would have been obvious to one of ordinary skill in the art at the time the invention was made. (Final Rejection 3-4; Ans. 4, 6).

Boston Scientific cites several sections of the Liu reference and concludes that one skilled in the art would not have been motivated to modify Liu to add a cap to the *second entry* [4] to prevent contamination or leaking of fluids at the proximal end. (App. Br. 5-6, emphasis added). Boston Scientific also argues that (1) it is not apparent that adding a cap to Liu's device would actually be desirable for further reducing leaks and/or contamination since Liu already has a device for preventing leaks (i.e., valve [5]); (2) there is no support in the record to explain why one skilled in the art would have been motivated to go through the additional cost and complexity associated with adding a cap to Liu's device; and (3) there is no evidence of record that indicates that Liu's approach to preventing leaks does not work. (Reply Br. 2).

Although Boston Scientific indicates that all claims stand or fall together, Boston Scientific's "cap" arguments seem directed to the limitations of dependent claims 7 and 16. Independent claims 1, 10 and 19 do not require a cap on the second entry (i.e., the proximal end of the side-

arm tube [4]). However, dependent claims 7 and 16 do. Claims 7 and 16 each recite “the cap is adapted to seal a proximal end of the side-arm tube . . .”. (App. Br. 10, 12). In any event, we address the argument with respect to dependent claims 7 and 16.

The Examiner finds that Fischell describes a cap [80] for sealing the system to reduce blood loss when inserting guiding catheters/rods/wires i.e., intervention devices. (Final Rejection 3; Ans. 4, citing figs. 1-3 and 7). Fields describes a similar arrangement of a cap [41] for sealing. (FFs 12-13). The Examiner determined that it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Liu and Davidson with a cap for the side arm in order to reduce blood loss when inserting the wire into the side arm. (Final Rejection 3; Ans. 4).

Boston Scientific does not present objective evidence to support its argument that one skilled in the art would not have been motivated to modify the combination of Liu and Davidson to add a cap to the second entry [4] to prevent contamination or leaking of fluids at the proximal end. Equally unpersuasive are Boston Scientific’s arguments that (1) there is no motivation or apparent desirability to add a cap to Liu’s device, and (2) no evidence has been presented to show that Liu’s approach to preventing leaks does not work. In determining obviousness, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. In this case, one with ordinary skill in the art at the time the invention was made would have recognized the benefits of providing an additional seal to prevent blood loss

for redundancy should the first seal unexpectedly fail. (FF 2). “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR at 1742*. Furthermore, modifying the combination of Liu and Davidson to include a cap for the side arm would have been obvious to one with ordinary skill in the art because the combination of familiar elements according to known methods is obvious when it does no more than yield predictable results. Boston Scientific does not present evidence to demonstrate that the combination yields unpredictable results.

For these additional reasons, Boston Scientific does not demonstrate that the Examiner erred in determining that claims 1-26 would have been obvious.

F. CONCLUSION

1. Boston Scientific has not demonstrated that Liu does not describe a catheter.

2. Boston Scientific has not demonstrated that the Examiner erred in determining that the claimed invention would have been obvious based on the rationale provided by the Examiner for combining the references.

G. ORDER

The decision of the Examiner rejecting claims 1-26 under 35 U.S.C. § 103(e) as unpatentable over Liu, Davidson, and Fischell or Fields is affirmed.

No time period for taking any subsequent action in connection with the appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Appeal 2009-0508
Application 10/690,436

MAT

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catheter (kath'e-ter)

1. A tubular instrument to allow passage of fluid from or into a body cavity or blood vessel (blood vessel). SEE ALSO: line (4) . 2. Especially a c. designed to be passed through the urethra into the bladder to drain it of retained urine. [G. *katheter*, 1 fr. *kathienai*, 1 to send down]

acorn-tipped c. a c. used in ureteropyelography to occlude the ureteral orifice and prevent backflow from the ureter during and following the injection of an opaque medium.

angiography c. a thin-walled tube suitable for percutaneous insertion and power injection of contrast media for radiography; c. diameter is measured on the French scale. See Seldinger technique.

balloon c. a c. used in arterial embolectomy or to float into the pulmonary artery.

balloon-tip c. a single- or double-lumen tube with a balloon at its tip that can be inflated or deflated without removal after installation; the balloon may be inflated to facilitate passage of the tube through a blood vessel (blood vessel) (propelled by the bloodstream) or to occlude the vessel in which the tube alone would allow free flow; such c. are used to enter the pulmonary artery to facilitate hemodynamic measurements. SEE ALSO: Swan-Ganz c..

bicoudate c., c. bicoudé (bi-koo-da') an elbowed c. with a double bend. [bi + Fr. *coudé*, bent]

Bozeman-Fritsch c. a slightly curved double-channel uterine c. with several openings at the tip.

Braasch c. a bulb-tipped c. used for dilation and calibration. SYN: Braasch *bulb*.

Broviac c. a type of long-term central venous c. with an external port for administration of medication.

brush c. a ureteral c. with a finely bristled brush tip that is endoscopically passed into the ureter or renal pelvis and by gentle to-and-fro movement brushes cells from the surface of suspected tumors.

cardiac c. SYN: intracardiac c..

central venous c. a c. passed through a peripheral or central vein, ending in the superior vena cava or right atrium, for measurement of central venous pressure or for infusion of hyperosmolar solutions.

conical c. a c. with a cone-shaped tip designed to dilate the ureter.

c. coudé (koo-da') a c. with an angular bend near the beak; used to rise over prostatic obstruction. SYN: elbowed c., prostatic c.. [Fr. *coudé*, bent]

c. à demeure (a-dem-ër') an obsolete term for a c. that is retained for a considerable period in the urethra. [Fr. *demeurer*, to dwell]

de Pezzer (de Pezzer) c. a self-retaining c. with a bulbous extremity.

double-channel c. a c. with two lumens, allowing irrigation and aspiration or injection and pressure measurement. SYN: two-way c..

elbowed c. SYN: c. coudé.

eustachian c. a c. for the middle ear through the eustachian tube.

female c. a short, nearly straight c. for passage into the female urethra.

Fogarty embolectomy c. a c. with an inflatable balloon near its tip; used to remove emboli and thrombi from blood vessels or to remove stones from the biliary ducts.

Foley c. urethral c. with a retaining balloon.

Gouley c. a solid curved steel instrument grooved on its inferior surface so that it can be passed over a guide through a urethral stricture.

Hickman c. long-term, central venous indwelling c. with external port(s).

indwelling c. a c. left in place in the bladder, usually a balloon c..

intracardiac c. a c. that can be passed into the heart through a vein or artery, to withdraw samples of blood, measure pressures within the heart's chambers or great vessels, and inject contrast media; used mainly in the diagnosis and evaluation of congenital, rheumatic, and coronary artery lesions and to evaluate systolic and diastolic cardiac function. SYN: cardiac c..

Malecot c. a two- or four-winged c..

Nélaton c. a flexible c. of red rubber.

olive-tipped c. a ureteral c. with an olive-shaped tip, used to dilate a constricted ureteral orifice; larger sizes are also used for dilating or calibrating urethral strictures.

pacing c. a cardiac c. with one or more electrodes at its tip which can be used to artificially pace the heart.

Pezzer c. See de Pezzer (de Pezzer) c..

Phillips c. a c. with a filiform guide for the urethra.

pigtail c. a c. with a tightly curled end and multiple side holes to reduce the impact of the injectant on the vessel wall or to remain in a chamber or space for drainage.

prostatic c. SYN: c. coudé.

pulmonary artery c. SYN: Swan-Ganz c..

Robinson c. a straight urethral c. with two to six holes to facilitate drainage, especially in the presence of blood clots which may occlude one or more openings.

self-retaining c. a c. so constructed that it remains in urethra and bladder until removed, e.g., indwelling c. Foley c..